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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,168	11/06/2001	Merrit N. Jacobs	CDS-256	8482

27777 7590 04/18/2007  
PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER
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FOSTER, CHRISTINE E

ART UNIT	PAPER NUMBER
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1641

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/993,168		JACOBS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Christine Foster		1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21,22,24,25 and 30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21,22,24,25 and 30 is/are rejected.
- 7) ☒ Claim(s) 21 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/6/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/11/06 has been entered.

2. Please note that the Examiner in this application has changed. The new Examiner, Christine Foster, may be reached at 571-272-8786.

### *Rejections Withdrawn*

3. The rejections of claims 21, 24-25 and 30 under 35 USC 103(a) as being unpatentable over Cusack et al. in view of Mintz and Shepherd et al., and of claim 22 under 35 USC 103(a) as being unpatentable over Cusack et al., Mintz, Shepherd et al., and Zabetakis et al., have been withdrawn pursuant to consideration by the Examiner because the references fail to teach or suggest scanning a 10% portion of the liquid within the second cavity that is closest to the first cavity. Specifically, since Cusack et al. teach placement of the photosensors 81 and 82 proximate to the first cavity (wider region 30), the liquid in the first cavity is scanned rather than the liquid in the second cavity (narrow region 44; see Figure 8b of Cusack et al.).

### *Specification*

4. The specification is objected to for the following reason:

Applicant is requested to update the specification on page 1 to reflect the most current priority status of the present application, including proper reference to applications that have been issued or abandoned. Specifically, the reference to application 09/510,928 should be amended to reflect the issuance as US 6,641,993.

5. The abstract of the disclosure is objected to because:

Applicant is requested to amend the abstract in order to reflect the elected invention of a method for determining the strength of an agglutination reaction. See MPEP § 608.01(b).

### *Claim Objections*

Claim 21 objected to because of the following informalities: in part b) the claim recites that the mixture is transferred “to a second cavity”, but the claim does not make clear that the second cavity is also part of the probe tip mentioned in part a). It is suggested that part b) refer to “a second cavity of the probe tip” in order to avoid confusion.

### *Drawings*

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description:

7. In Figures 3 and 4 appear to contain the reference character “ $\alpha$ ”, which is not described in the specification (see near reference numeral 128, the transition zone in both figures).

8. In Figure 4, the reference character “A” is also not described in the specification.

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9. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 21-22, 24-25, and 30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

12. Claim 21 recites in step (c) the step of "scanning a 10% portion of the liquid", which was introduced by Applicant's amendment of 8/29/05. The claim as originally filed recited simply "scanning the liquid". The amendments represent a departure from the specification and claims

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as originally filed because although the claim previously referred to a “10% portion” in steps (c) and (d), there was no prior mention that the 10% portion referred to a portion of the *liquid*.

Applicant states that the amendment was made in order to provide antecedent basis for “said 10% portion”, but did not specify where support may be found in the specification (see p. 5 of the reply of 8/29/05). The specification refers to a “10% portion” at p. 6, lines 10-27. However, this passage, like the original claim, also fails to state that the 10% portion refers to a portion of the liquid. The specification does not disclose “scanning a 10% portion of the liquid” as currently claimed.

Since the reference to “said 10% portion being that portion closest to said first cavity” could also conceivably refer to a 10% portion of the *second cavity* (for example), Applicant has not established that the amendment represents correction of an obvious error since there is nothing of record to indicate that one skilled in the art would not only recognize the existence of the error in the specification, *but also recognize the appropriate correction*. In re Oda, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971). See MPEP 2163.

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claim 21 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. Claim 21 recites the step of “scanning a 10% portion of the liquid within said second cavity during said step b)...said 10% portion being that portion closest to said first cavity”. The

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claim is indefinite because the reference to the 10% portion closest to the first cavity would seem to suggest that all of the liquid is contained within the second cavity, and that 10% of this liquid is scanned—specifically, the 10% that is closest to the first cavity. However, since the recited scanning step occurs **during** the transferring step that is recited as step b), in which the mixture is transferred from the first to the second cavity, not all of the liquid would be in the second cavity since the liquid is in the process of being transferred from the first to the second cavity. As a result, it is unclear what is meant by the references to a “10% portion”. Is only 10% of the total liquid scanned? Or is all of the liquid scanned, but only 10% at a time as it is transferred from the first to the second cavity? For all of these reasons, the metes and bounds of the claim cannot be determined.

16. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a positive process step in which the strength of an agglutination reaction is determined. The body of the claim recites step (g) of calculating the *amount* of agglutination, which does not clearly relate back to the method objective of determining the *strength* of an agglutination reaction as recited in the preamble of the claim. Alternatively, a correlation step may be included that clearly relates the results of the assay back to the method objective as recited in the preamble.

17. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the other component of the agglutination reaction.

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The claim refers to an “agglutination reaction” and includes the step a) of providing a mixture of a liquid sample and an “agglutinating reagent”. Step f) refers to separation of “agglutinated material” from “non-agglutinated material”. However, nowhere in the claim is it stated the components of the agglutination reaction are. Presumably, the agglutinating reagent is one of the components—what is the other? In order for an agglutination reaction to occur, a second component or material would be essential; such a second component is not recited in the claims.

It would also seem that the component to be agglutinated by the agglutinating reagent is contained in the liquid sample, but this is not clear. It is also unclear what the components of the “agglutinated material” and the “non-agglutinated material”. The claim fails to make clear that the agglutinated material is formed by an agglutination reaction between the agglutinating reagent and some component in the sample.

18. Claim 21 recites the limitation “the liquid” in step (c). There is insufficient antecedent basis for this limitation in the claim. Step (a) refers to “a liquid sample” and not to a liquid *per se*. Furthermore, since the liquid sample is mixed with an agglutination reagent (which may be either liquid or solid form), it is unclear whether “the liquid” is referring only to the liquid sample or to the mixture. See also claim 22.

19. Claim 21 recites the limitation “the amount of agglutination” in step (c). There is insufficient antecedent basis for this limitation in the claim.



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***Response to Arguments***

20. Applicant's arguments filed 12/8/06 have been fully considered but are moot in light of the withdrawal of the rejections under 35 USC 103(a) for the reasons set forth above.

***Conclusion***

21. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Treptow et al. (US 5,844,686) teaches an apparatus for pipetting and photometrically evaluating samples (see especially Figure 1) comprising a pipette tip 4 having a first cavity or portion of larger diameter than a second cavity (cone portion 11). However, in Treptow et al. the sample is scanned in the first larger cavity and not in the second narrower cavity.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christine Foster, Ph.D.  
Patent Examiner  
Art Unit 1641



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